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0. Medical Devices overview

Medical devices include everything from highly advanced CT scanners down to simple wooden tongue depressors, and from contact lenses to malaria test-kits to hospital beds. The primary mode of interaction of a medical device with the human body is not metabolic, immunological, or pharmacological, in contrast with that of medicinal products. Medical devices include instruments, reagents, software, or materials, to be used for human beings, for purposes such as:

- Diagnosis, prevention, monitoring, treatment, alleviation of a disease or injury

- Investigation, replacement, modification or support of the anatomy or a physiological process
- Support or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information for medical purposes.
- Aids for disabled/handicapped people (not considered to be medical devices by some classifications).

The WHO provides a full definition¹. Several different classification systems for medical devices are in use. The Global Harmonization Task Force on Medical Devices has laid the ground work for a harmonized nomenclature, on which the International Medical Devices Regulators Forum² continues to build upon to create a single, global definition and nomenclature.

The FDA distinguishes 3 classes of medical devices based on the patient risk involved (comparable to the 4 class system used in the EU):

- Class I medical devices have the least amount of regulatory control. They present minimal potential harm to the user. Class I devices are typically simple in design, manufacture and have a history of safe use. Typical examples are tongue depressors, arm slings or stethoscopes.
- Class II medical devices have the potential to pose a mild risk to a patient if used incorrectly, either on the short or long term. Typical examples are physiologic monitors, x-ray systems, insulin pens or some pregnancy tests.
- Class III medical devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. They require pre-market approval based on medical scientific study. Typical examples are pacemakers and life support systems, but also HIV diagnostics³

All three classes are relevant to developing countries. For this overview, the focus is on medical devices used in treatment of those living in poverty⁴. These can be medical devices used at a local public hospital or field clinic, which are either purchased via a grant or have been donated by a charity, or medical devices specifically designed for low-income setting, so called “appropriate technology” or “frugal design”. This means we exclude medical devices targeted specifically at middle or upper income levels, such as those used in private clinics, high-tech, Western medical devices that are being used by Western doctors in humanitarian situations.

We exclude ‘general health products’ that are sold over the counter rather than via a specialized medical channel, such as women’s menstruation products, condoms, mosquito nets or water purification devices.

¹ http://www.who.int/medical_devices/full_definition/en/index.html

² <http://www.imdrf.org/about/about.asp>

³ <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm>

⁴ See appendix 5

This document is based on information being available in 2013.

Key takeaways are noted in the boxed sections.

1. Market demand

1.1. Market description

- **In developing countries, communicable diseases and environmental issues are the biggest causes of death and disease burden.**
- **As welfare increases, so does the incidence of chronic illnesses such as diabetes and cardiovascular diseases.**
- **There is a lack of global attention for health conditions which have a far more complex cause than communicable diseases, such as chronic diseases, upper respiratory tract infections, or diarrhea.**

Medical devices are aimed to prevent, treat, diagnose or alleviate diseases or health conditions. Therefore, the market for such devices is defined by people suffering from those afflictions.

- In low-income countries, 40% of deaths occur in children under 15 years, and only 20% in people aged 70 or older. People die predominantly of infectious diseases such as respiratory infections, HIV/AIDS, diarrheal diseases or malaria, or complications around childbirth.⁵
- In comparison, in high-income countries, 70% of deaths are among people aged 70 or older. People die predominantly of chronic diseases such as cardiovascular diseases, cancers or dementia. Less than 1% of deaths is among children under 15 years.⁶
- The top-10 causes of death in low-income and lower-middle income countries are:⁷

Low income countries	lower-middle income countries
1. Lower respiratory infections	1. Ischemic heart disease
2. HIV/AIDS	2. Stroke
3. Diarrheal disease	3. Lower respiratory infections
4. Stroke	4. COPD
5. Ischemic heart disease	5. Diarrheal diseases
6. Infant prematurity	6. Prematurity
7. Malaria	7. HIV/AIDS
8. Tuberculosis	8. Tuberculosis
9. Protein energy malnutrition	9. Diabetes mellitus
10. Birth asphyxia and birth trauma	10. Road injury
- Injury due to traffic accidents has the highest occurrence in middle-lower income countries, where motorized transportation is widespread but unsafe.

⁵ <http://www.who.int/mediacentre/factsheets/fs310/en/index2.html>

⁶ <http://www.who.int/mediacentre/factsheets/fs310/en/index2.html>

⁷ <http://www.who.int/mediacentre/factsheets/fs310/en/index1.html>

- In developing countries, up to 35% of death and disease can be attributed to preventable, environmental causes, either at work, at home, or in the broader community/living environment⁸. Main causes are:
 - Unsafe water and poor sanitation and hygiene, leads to the spread of diseases such as cholera and diarrhea.
 - Indoor smoke – primarily from the use of solid fuels in domestic cooking and heating leads to respiratory diseases.
 - Urban air pollution generated by vehicles, industries, and energy
 - Malaria, mostly African children under the age of five.
 - Poorly designed irrigation and water systems, inadequate housing, poor waste disposal and water storage, deforestation and loss of biodiversity, all contribute to the spread of common vector-borne diseases, including malaria, dengue and leishmaniasis.
 - Degradation of the built urban and rural environment, and an increase in motorized transportation leads to road traffic injuries. Low- and middle-income countries bear 90% of the death and injury toll.
 - Poisonous or toxic elements naturally present in the environment, such as lead, arsenic or fluoride lead to death, disability or cognitive effects.
 - Climate change impacts, including more extreme weather events, changed patterns of disease and effects on agricultural production.
 - Excessive exposure to, and inappropriate use of, toxic chemicals and pesticides present in occupational and/or domestic environments.
- As countries are gradually developing, the occurrence of infectious diseases (such as malaria, diarrhea) typically decreases, while the occurrence of chronic, age related diseases increases (such as diabetes or heart conditions).
- Global attention is more focused on communicable diseases such as HIV/AIDS and malaria, than on health conditions which have a far more complex cause, such as upper respiratory tract infections or diarrhea, or chronic diseases.
- Fake drugs and fake diagnostics are an increasing problem. In 2011, 64% of imported malaria medication into Nigeria was fake⁹.

1.2. Impact description

- **Low skilled community health workers are increasingly being depended on for basic healthcare services.**
- **Specially designed easy-to-use medical devices and information technology allows them to perform tasks previously reserved to high skilled professionals.**

Medical devices are used in medical treatments to prevent, diagnose, treat or alleviate diseases or health conditions. The impact of medical treatment can be described both in health-related terms, as well as in socio-economic terms.

- Health

⁸ <http://www.who.int/heli/risks/ehindevcoun/en/index.html>

⁹ <http://www.economist.com/node/21564546>

- Effective medical treatment is aimed at increasing a person's lifespan, or increase quality of life, or both. Health economists use concepts such as "Disability Adjusted Life Years" (DALY)¹⁰ to assess the effectiveness of a treatment in relation to cost.
- Timely treatment of communicable diseases slows further spread of the disease.
- Socio-Economic
 - When effective, a treatment gives people more "Disability Adjusted Life Years", in which they are better able to add economic (or social) value. In healthcare economics, the cost related to prevention are often significantly lower than the cost related to curing a condition.
 - Generally speaking, the healthcare sector employs relatively high-skilled people, creating little jobs for those living at the base of the pyramid (in contrast to sectors such as agriculture, where the majority of the workforce employed is from low socio-economic status).
 - In many developing countries, there is a critical shortages of skilled healthcare professionals. Training centers cannot keep up with increasing demand for healthcare services, migration, deaths from AIDS and other diseases, low workforce productivity and population growth.
 - Skilled healthcare professionals who prefer to pursue a career abroad after finishing their education leads to a local brain-drain¹¹. However, a countertrend is for highly skilled professional migrating back to their home countries when economic, social and political conditions are improving.
 - Low skilled community health workers are increasingly being depended on for basic healthcare services (using a system of task shifting from high to low skilled personnel), often with promising results¹².

1.3. End-user behavior trends

- **Chronic and multi-vector diseases are increasing due to increased increases in life expectancy and changing urban lifestyles.**
- **Mobile information technology give patients and healthcare professionals easier and more cost-effective access to medical information**
- **Universal healthcare and inclusive finance give people increased access to medical systems. However, increased patient inflow reduces the quality of care that can be delivered.**

The trends below have an effect on health conditions or on the availability or effectiveness of medical treatments. Both medical staff as well as patients are considered as end-users.

- Urbanization:
 - People living in cities have better access to health care systems, although public hospitals tend to be overcrowded, and offer poor quality.

¹⁰ http://www.who.int/healthinfo/global_burden_disease/metrics_daly/en/

¹¹ <http://www.ncbi.nlm.nih.gov/pubmed/19484878>

¹² http://www.who.int/healthsystems/task_shifting/TTR_tackle.pdf

- High population density in combination with low hygiene leads to an easier spread of communicable diseases
- Changing urban food patterns lead to increases in conditions previously associated with the 'West', such as diabetes, heart attack and obesity.
- Increasing outdoor air pollution in cities leads to diseases of the respiratory tract, various cancers, etc.
- Increased life-expectancy
 - Successes in the fight against infectious diseases, better nutrition and fewer conflicts (amongst others) have increased life expectancy in developing countries. Therefore, chronic illnesses such as diabetes and heart attacks are accounting for a growing percentage of health conditions in developing countries.
- Universal health care
 - Citizens are demanding affordable access to medical systems. Governments in developing countries are increasingly accommodating universal health care. In reality, many healthcare systems are not able to handle the inflow of new patients, or are chronically underfunded¹³.
 - In countries with poor public health care facilities, private health care is the preferred option for those who can afford it.
- Mobile phones
 - Mobile phones give patients and healthcare professionals easier and more cost-effective access to medical information
 - Mobile phone based diagnostic systems function as early warning systems for outbreaks of communicable diseases in remote areas
- Inclusive finance
 - Micro-credit and micro-insurance schemes are new ways to allow the poor to be able to pay for medical treatments

2. Market supply state

2.1. Product landscape

- **Medical devices specifically designed for low-resource settings are an upcoming product segment. Those low-cost devices are expected to also influence Western markets.**
- **The sector relies heavily on donations of medical equipment, which - when not properly coordinated - can have negative outcomes.**

The product landscape for medical devices is very diverse. Over 8000 generic medical device groups are recognized¹⁴. Categories that are often associated with specific use in developing countries are:

- Devices related to maternal health care, such as infant incubators
- Devices for diagnostics, such as reagent kits/blood tests
- Devices aimed at physical disabilities, such as prostheses, wheelchairs or glasses
- Basic imaging equipment, such as microscopes or ultrasound devices

¹³ <http://www.irinnews.org/report/97658/indonesia-aims-for-universal-health-care-by-2019>

¹⁴ <http://www.efta.int/eea/policy-areas/goods/product-sectors/medical-devices>

- Basic medical supplies and equipment, such as needles, syringes.

Many very specific devices exist, such as a device for male circumcision¹⁵ in Uganda or a mobile phone based application that allows remote rural clinics in Senegal to send and receive tuberculosis test results¹⁶. Some medical devices are specifically designed for a specific cultural or institutional context.

Within those products, another categorization can be made:

- Generic medical devices, aimed at the global market. Most medical devices are designed for high-income countries, and will trickle down into developing countries, usually first in private clinics before becoming available in the public health sector, in some cases as second hand or donated equipment.
- Medical devices specifically designed for low resource settings, usually with a focus on low cost, low skill and maintenance requirements, and low energy needs. These products can be scaled down versions of high-end medical devices, but can also be complete redesigns, deviating in form and performance from generic medical devices.
 - Frugal innovation¹⁷ is an upcoming term to describe product innovations for low-resource settings. Some examples are:
 - Jaipur Foot¹⁸, a series of foot prostheses.
 - Firefly¹⁹, a baby phototherapy device
 - Q-mat²⁰, a standardized mat to measure bleeding during childbirth.
 - Some low-cost medical devices that were specifically designed for low-income countries have been successful in the high-income market, which is increasingly price-sensitive. This is dubbed Reverse innovation²¹. Examples are low cost infant incubator designs from India²² entering Western markets.
- Health institutions of many low-income countries rely significantly (up to 80%) on donations of medical equipment²³. These donations are made with good intentions; however, if the donations are not well planned and coordinated the outcomes can be negative, due to little consideration for:
 - Local requirements
 - Burden of disease and level of care
 - Number of users, maintenance personnel, and their capabilities
 - Availability of consumables or spare parts
 - Electrical compatibility, or availability of gas or water connections
 - Cultural differences and expectations on both sides of the donation²⁴

¹⁵ <https://me-web2.engin.umich.edu/pub/news/newsitem?newsItemId=454>

¹⁶

¹⁷ http://en.wikipedia.org/wiki/Frugal_innovation

¹⁸ <http://jaipurfoot.org/>

¹⁹ https://static.squarespace.com/static/5267f3a6e4b0da2bab9939e3/t/528be4ade4b0249b3814f695/1384899757089/Firefly_Phototherapy_Brochure.pdf

²⁰ <http://www.icddrb.org/media-centre/feature/the-q-mat-an-innovative-solution-to-reduce-maternal-mortality>

²¹ http://en.wikipedia.org/wiki/Reverse_innovation

²² <http://www.bbc.co.uk/news/business-23817127>

²³ http://www.who.int/medical_devices/management_use/donations_training_module.ppt

²⁴ <http://www.thet.org/hps/resources/medicalequipment/medical-equipment-donations>

2.2. Supply chain

- **The Western private sector is under involved in medical device R&D for developing countries due to the long time-to-market and low perceived opportunity.**
- **India and China are hosting an increasingly sophisticated low-cost medical device design and manufacturing industry.**
- **Device manufacturers are more-and-more offering on-site training and maintenance.**
- **The absence of end-of-life coordination, especially for donated equipment leads to waste and health issues.**

A generalized description of the supply chain for medical devices is detailed below. Donated or second hand medical devices can follow a complex supply chain between first and second users, which is not described in detail here.

- **R&D and design:**
For medical devices, R&D and design are heavily interrelated, as form often follows medical function. R&D and design teams usually consist of partnerships between universities and NGO's. The private sector is under involved in R&D and design trajectories due to the length and risk of the regulatory process in developing countries versus a perception of limited commercial opportunities.
- **Production:**
Products are generally manufactured in Western countries or in Asia. India and China host an increasingly sophisticated medical device production industry, which is fueled by local demand. This industry is better positioned than Western producers to provide low-cost medical devices to developing countries.
- **Assembly:**
Local assembly is chosen when it fits with the complexity of the product, as well as the business model and/or mission statement of the organization bringing the product to the country.
- **Distribution:**
Distribution is a key issue, which is often overlooked when a new concept for a medical product is being developed. Due to a lack of e.g. pan-African regulations, entering a new geography with a proven medical product from neighboring country can take a long time.
- **Training and Maintenance:**
Training on how to use the devices is either done by NGO's or a company that is rolling out the product. Usually, train-the-trainer schemes are set-up to reduce cost. Multinational medical device companies are more and more offering training and maintenance in packages together with the purchase of equipment. Healthcare equipment donations often lack sufficient training or maintenance. Frugal solutions generally are designed to require as little maintenance as possible, although some maintenance and training is still required, and wrong use can lead to serious health issues.
- **End-of-life:**
Programs dealing with the end-of-life of medical devices are virtually absent in developing

countries. 40% of donated equipment goes unused²⁵, causing a significant waste issue. The improper discarding of medical devices can pose serious health issues to those who try to re-use them.

2.3. Revenue models

- **The majority of medical devices is funded via public or NGO means.**
- **Social entrepreneurs are experimenting with (semi)commercial business models to introduce medical devices to developing countries in a financially sustainable way.**

Medical treatment aimed at low-income patients is generally not seen as a profitable business activity. Traditionally, local healthcare systems rely on public funding or NGO involvement. Many medical devices are given away for free. A trend is for medical device companies to be organized as a social business, combining financial sustainability with achieving impact at scale. Health entrepreneurs are experimenting with new models for a business-like approach to medical treatment in developing countries. Some examples:

- **Mixed revenue models:** Social businesses will typically form public private partnerships, and rely on a mix of government funding, donor money and return on sales. The social business that created the Jaipur foot, which is considered one of the most successful frugal medical devices, depends for 60% on donations, 30% on government support, and 10% on earned income.²⁶
- **Mass service delivery:** Narayana Hrudayalaya Hospital in India has 30.000 beds, where patients receive highly standardized heart surgery at a fraction of the cost of Western, more taylor-made healthcare²⁷.
- **Cross subsidy model with tiered pricing / proportional payment:** Lifespring hospitals²⁸ offers different prices for different types of rooms to give birth in (communal, semi-private, private), where part of the revenues from the private rooms are used to make the communal rooms as affordable as possible.
- **Combination of health services with other services.** Health Point²⁹ operates rural kiosks where health services are being combined with ICT services and drinking water, while Health Hub³⁰ uses an existing kiosk infrastructure to also distribute health services.
- **The use of mobile phone technology to significantly improve information cost and timeliness:** CliqMedix³¹ offers a low-budget, easily scalable e-health information, diagnostics and treatment system through a smartphone app or web browser.

²⁵ <http://healthland.time.com/2012/08/06/report-why-40-of-donated-medical-equipment-goes-unused-in-poor-countries/>

²⁶ http://jaipurfoot.org/media/feature_stories/partnering_technology.html

²⁷ <http://www.narayanahealth.org/>

²⁸ http://www.businesscalltoaction.org/wp-content/files_mf/bctalifespringcasestudy.forweb29.pdf

²⁹ <http://ehealthpoint.com/>

³⁰ <http://www.businesscalltoaction.org/members/2013/06/hapinoy/>

³¹ <http://clickmedix.com/>

- Two-sided business models: mobile health startup M-Pedigree offers a free SMS-based drug verification service. Pharmaceutical companies who benefit from limiting drug counterfeiting pay for each SMS sent³².

Most frugal medical devices are yet to be introduced to the market place at sufficient scale to prove the success of new (semi)-commercial business models.

2.4. Industry structure / Market leaders

- **Religious charity organizations dominate the medical device donation market.**
- **Future market leaders in medical devices for developing countries might not be Western multinationals, but come from India or China, or from frugal design**
- Health institutions in developing countries rely significantly on donated equipment. Donations are typically done by religious charity organisations.
- Multinational medical device manufacturers such as GE Healthcare and Philips Medical³³ are increasingly focusing their strategy on developing countries. However, experts indicate they are struggling to overhaul their existing business rationale to successfully accommodate designing, producing and distributing ultra-low cost devices.
- Chinese and Indian players are starting to export their products to less-developed countries.
- Given the youth of the field, and the long regulatory processes, many 'frugal' medical devices have yet to enter the market. Organizations leading the way in frugal design are typically not-for-profits, either directly marketing their product in developing countries (such as Jaipur Foot) or licensing their designs to local players (such as D-Rev and Designs that Matter).

3. Knowledge state

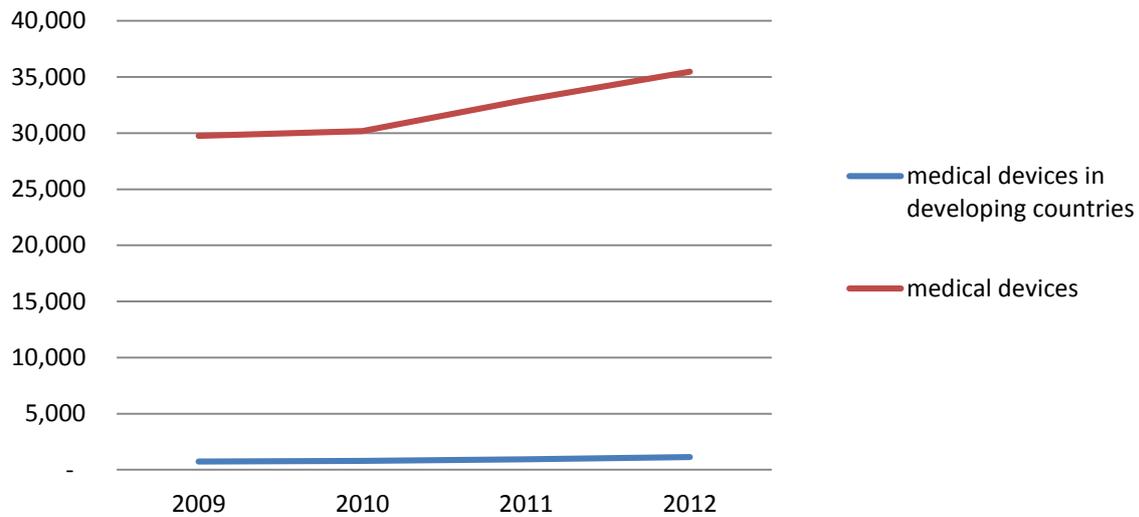
3.1. R&D Intensity

- **R&D intensity for medical devices for developing countries is increasing rapidly, and outpacing sectors such as water, agriculture and energy.**
- **Much research is dedicated to adapting existing treatments to a local context**

³² <http://www.businessweek.com/stories/2008-12-03/mpedigrees-rx-for-counterfeit-drugsbusinessweek-business-news-stock-market-and-financial-advice>

³³ <http://allafrica.com/stories/201305160015.html>

Peer reviewed articles published per year



- Yearly, around 35,000 scientific articles are published that cover a topic on medical devices. Out of those, roughly 1,100 (3%) focus specifically on developing countries.
- The R&D effort is growing significantly. The amount of articles published yearly on medical devices in developing countries is growing at 15%, compared to 6% a year on R&D for medical devices in general. Development specific research in other sectors grows slower (agricultural processing 13%, renewable energy 7%, water treatment 4%).
- The WHO estimates growth in research investment in medical devices in the Western world to be 0%, while investment in developing countries is growing at 5%.³⁴
- Experts indicate that a large amount of R&D is not focused at fundamentally new treatments, but at new procedures or new devices to adapt a treatment to a local context in a developing country. Differentiating factors can be low-tech, easy maintenance, low-cost, energy-efficient, but also specific cultural norms among local populations or ethnicities.
- Emerging economies, especially China, India and Brazil, are producing more and more authors of published research. However, publications are often done in co-authorship with Western academics.
- Many medical universities in developing countries are in some way affiliated to a Western university, such as Ifakara Center in Tanzania which is affiliated to the Swiss Tropical and Public Health Institute³⁵.
- In the US, the field of 'appropriate medical devices' is recently starting to take shape by an inflow of biomedical engineering PhD students. Most have followed undergraduate courses on appropriate technologies at universities such as University of Michigan, Rice, Northwestern or Duke, and chose to specialize in this subject.

³⁴ http://www.who.int/whr/2013/main_messages/en/index.html

³⁵ <http://www.swisstph.ch/en.html>

3.2. R&D centers, journals and conferences

- **Other than in the water, energy or agriculture sector, Western universities (still) dominate medical device R&D.**
- **The amount of open-access publications is higher than in other sectors.**

The following universities and R&D centers have published the highest number of scientific articles medical devices specifically focused on developing countries (2011 – 2013), or were indicated by experts as leaders in the field.

- World Health Organisation, Geneva, Switzerland
- London School of Hygiene & Tropical Medicine, London, United Kingdom
- Johns Hopkins Bloomberg School of Public Health, Baltimore, United States of America
- University of California San Francisco, San Francisco, United States of America
- University of Ibadan, Ibadan, Nigeria
- All India Institute of Medical Sciences, New Delhi, India
- University of Washington Seattle, Seattle, United States of America
- Massachusetts General Hospital, Boston, United States of America
- Muhimbili University of Health and Allied Sciences, Dar-es-Salaam, Tanzania
- University of Benin, Benin City, Nigeria
- University of Cape Town, Cape Town, South Africa
- Cairo University, Cairo, Egypt
- Centers for Disease Control and Prevention, Atlanta, United States of America
- University College London, London, United States of America
- Harvard Medical School, Boston, United States of America
- Johns Hopkins University, Baltimore, United States of America
- University of Ghana, Accra, Ghana
- Columbia University in the City of New York, New York, United States of America
- Obafemi Awolowo University, Ife Ile, Nigeria
- Karolinska Institutet, Stockholm, Sweden
- Rice University, Houston, United States of America
- Duke University, Durham, United States of America
- Northwestern University, Chicago, United States of America
- University of Michigan, Ann Arbor, United States of America
- Royal Tropical Institute, Amsterdam, The Netherlands

The following journals contain the highest number of articles on medical devices for developing countries (2011 – 2013):

- Plos One
- World Journal of Surgery
- Malaria Journal
- Pan African Medical Journal
- International Journal of Gynecology and Obstetrics
- Lancet

- Journal of Clinical and Diagnostic Research
- Contraception
- BioMedCentral Public Health
- Journal of the Pakistan Medical Association
- Journal of Acquired Immune Deficiency Syndromes
- BioMedCentral Pregnancy and Childbirth
- BioMedCentral Health Services Research
- Journal of the College of Physicians and Surgeons Pakistan
- Journal of Obstetrics and Gynecology of India
- Tropical Medicine and International Health
- African Health Sciences
- Eastern Mediterranean Health Journal
- BioMedCentral Research Notes

The following conferences are selected based on the amount of relevant articles published, or were indicated by experts. Scientific conferences typically focus on a single research area, and solutions dedicated to developing countries make up a small niche.

- Institute of Engineering and Technology Conference
- International Federation for Medical and Biological Engineering Conference
- IEEE Engineering in Medical and Biological Sciences Conference
- Society of Photo-optical engineers SPIE International Society for Optical Engineering Conference
- Association for Computing Machinery International Conference
- IEEE Global Humanitarian Technology Conference GHTC
- American Society for Engineering Education Annual Conference and Exposition
- IEEE Engineering in Medicine and Biology Society EMBS Conference
- Health Technology and Informatics Conference

Key take-aways:

- Even though local universities in developing countries (India, Nigeria, Pakistan) are publishing an increasing share of research on water purification for developing countries, 'Western' organizations –especially from the US - have a dominant role on this subject.
- There is ongoing debate about the general scientific quality of articles published in developing countries. Vanity publication and plagiarism are often mentioned occurrences in underdeveloped academic ecosystems. (The above list is created using the Scopus scientific index by Elsevier, which imposes certain quality controls). Other aspects that impact perceived quality can be a poor command of the English language, or unfamiliarity with the 'Western' scientific culture and traditions.
- Most European Institutes for Tropical Medicine, other than the British, are struggling with funding issues.
- The medical devices sector shows a high number of open access publications (PLoS One, BioMedCentral) compared to other sectors (energy, water, agriculture).

- Conferences tend to cover broad topics related to specific fields of engineering or medicine. Some conferences focus specifically on challenges related to developing countries (e.g. malaria), but typically focus more on treatment than on devices. Many conferences are sub-branches of engineering societies, which focus on a multitude of topics.

3.3. Technological trends

- **Global R&D is beginning to focus on low-cost solutions**
- **Most R&D is not purely technical in nature, but focused on adapting technology for a local context**
- **Technical R&D tends to focus on solving last-mile distribution issues**

- Global technological R&D for medical devices focuses on ever increasing quality and accuracy of medical treatment, as well as interoperability with information technologies and big data. However, recently a new focus on low-cost (or better: optimal-value) medical treatment is emerging.
- Major topics in R&D for developing countries are not technological in nature, but focus on adapting technology to the local context
 - The combination of medical technology research with design and ethnographic research. This tends to lead to very regionally specific solutions, which can be hard to scale to other regions.
 - Frugal innovation: designing medical devices specifically for low-resource settings (low cost, low maintenance, low skill required, low or stand-alone energy consumption)
- Technical R&D for developing countries focuses on improving last-mile distribution:
 - Point-of-care diagnostics, where doctors can do a test on-the-spot. Especially relevant for testing on non-communicable chronic illnesses such as diabetes, which are rapidly increasing.
 - Using mobile phone technology as a low-cost alternative to traditional medical information systems

3.4. Standardization and Test Centers

- **Due to a lack of national standards, practitioners often follow FDA or CE standardization.**
- **Regulations for medical devices are currently being harmonized over the continents.**
- **Uncertified products entering the market – many with the good intention “better something than nothing” - can cause negative health effects.**

- The medical sector is the most heavily standardized and regulated sector, due to its direct link to public health and safety, and its inherent complexity. Generally, the higher the potential risk involved, the more stringent regulations apply. The FDA uses the following regulations:
 - Class I: General controls, which include provisions relating to:
 - Adulteration;
 - Misbranding;
 - Device registration and listing;
 - Premarket notification;
 - Banned devices;
 - Notification and repair, replacement, and refund;
 - Records and reports;
 - Restricted devices; and
 - Good Manufacturing Practices³⁶
 - Class II: General controls and specific controls, which include provisions relating to:
 - Performance standards
 - Postmarket surveillance
 - Patient registries
 - Special labeling requirements
 - Premarket data requirements
 - Guidelines
 - Class III: General controls, specific controls and pre-market approval, which needs to be underpinned by scientific research and control trials.

- Developing countries face a large number of difficulties in formulating, implementing and enforcing process and product standards related to medical devices. Reasons are:
 - Inadequate institutional infrastructure and capabilities
 - Insufficient knowhow in standards development processes
 - Little awareness and little access to information on standardization
 - Limited participation in international standard setting
 - Poor coordination among agencies responsible for technical regulations
 - Inadequate funding
 - Inadequate stakeholder participation
 - Corruption

- In 2010, only 65% of countries had a national authority responsible for implementing and enforcing medical device regulations³⁷. A map showing which countries have national medical device testing agencies can be found here³⁸.

³⁶<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm>

³⁷ http://www.who.int/medical_devices/safety/en/

³⁸ http://gamapserver.who.int/mapLibrary/Files/Maps/Global_DIM_Indicator3_20110211.PNG

- When national standards are lacking, Western practitioners tend to follow FDA³⁹ or CE⁴⁰ regulations. Not all aspects in those regulations are directly applicable or useful for developing countries, and some aspects are lacking (e.g. working with very unreliable electricity grids).
- Medical experts argue that many uncertified medical products enter the market, often due to a “something is better than nothing” mentality, which can lead to serious health risks. An example is low-budget wheelchairs that offer poor comfort. This can lead to ulcerations and infections, for which treatment might not be available.
- Local practitioners reply by stating that “when lives can be saved by a quick and cheap innovation, even if results are not perfect, the device should be made available”⁴¹.
- Regulations for medical devices are being harmonized over continents.
 - The Pan African Harmonization Working Party is, in cooperation with the FDA, working on harmonizing pan-african regulatory frameworks for easier market entry⁴².
 - Develop a common register for diagnostic medical devices
 - Reducing duplication, costs and delays associated with regulatory audits
 - Reducing duplication of clinical trials for regulatory approval
 - Providing post-market surveillance
 - Standardizing rules to classify public health risks
 - The Association of South-East Asian Nations started a similar effort in 2004 by the Medical Device Product Working Group (MDPWG)⁴³, which will lead to implementation in 2014.

4. Support ecosystem

4.1. Funding and financing

- Available R&D funding aimed at medical devices for developing countries is limited
- Projects in healthcare can be very capital intensive, and prefer proven technology
- Impact investing in the medical devices for developing countries space is considered very risky and long-term, due to the regulatory pressure on the sector.

³⁹ <http://www.fda.gov/MedicalDevices/>

⁴⁰ http://ec.europa.eu/health/medical-devices/faq/market_en.htm

⁴¹ <http://events.imeche.org/EventView.aspx?loop=1&code=S1769>

⁴² <http://www.aslm.org/stay-informed/press-room/news-articles/pahwp-addresses-regulation-of-medical-devices-and-diagnostics-to-protect-public-health-in-africa/>

⁴³ <http://www.sgs.com/en/Our-Company/News-and-Media-Center/News-and-Press-Releases/2013/09/Harmonisation-of-Asias-Medical-Device-Industry.aspx>

The following trends can be observed in 3 types of funding that are relevant for medical devices in developing countries.

- R&D funding: fundamental and applied scientific research
 - both US and EU national research agendas have very limited funding available for medical device research specifically aimed at developing countries. Some funding programs are available for projects that focus on frugal and/or reverse innovation, but those aim at technologies being adopted in the West as low-cost alternatives
 - A growing majority of global R&D is financed by private, mostly multinational enterprises, such as GE Healthcare or Philips Medical, who increasingly acknowledge emerging economies as a focus area for growth. Typically these multinationals have regional R&D hubs in emerging economies.
 - Charities such as the Bill & Melinda Gates foundation are increasingly funding R&D aimed at pressing health issues in developing countries that get little attention in the West, such as malaria, tuberculosis or low-cost prosthetics. General R&D funding organizations such as the Wellcome Trust⁴⁴ are also known to fund development specific R&D projects.

- Project funding: projects aiming for impact without commercial objectives.
 - Funding comes from national programs (e.g. USAID, SIDA, DGIS, GTZ) or through fundraising by NGO's and charities. In many countries in the West, government funding of NGO's is under pressure.
 - Health care related projects are very capital intensive. The Global Fund to Fight AIDS, Tuberculosis and Malaria⁴⁵ has funded over 20 billion USD on projects from 2002 to 2013. 21% of that money was spent on health products and equipment.
 - Most NGO's prefer funding projects that implement proven technologies, leaving little room for technological or product innovation
 - Donations of medical equipment are often organized by faith-based organizations.

- Social business funding: businesses that combine a focus on reaching social or environmental impact with financial sustainability
 - Impact investors (venture capitalist who aim for both social/environmental as well as financial impact) are increasingly interested in funding start-up or scaling-up activities in developing countries.
 - However, the medical device sector is considered very risky due to the high cost and long timelines associated with clinical trials and regulatory processes. Limited investors are active in this space, and most spread their risk by also investing in other sectors.
 - Examples of impact investors in medical devices for developing countries are Acumen⁴⁶ and Insitor⁴⁷.

⁴⁴ <http://www.wellcome.ac.uk/>

⁴⁵ <http://www.theglobalfund.org/en/about/fundingspending/>

⁴⁶ <http://acumen.org/our-investments/?sector=health>

⁴⁷ <http://www.insitormangement.com/investments#>

- Some investors do not invest directly, but fund micro-credit for organizations rolling out local health services, such as GlobalPartnerships⁴⁸
- Especially for the development of innovative medical products and businesses, the “Pioneer Gap” poses an obstacle. The high cost and long timelines associated with clinical trials and regulatory processes are a main criterion. USAID DIV⁴⁹ or SIDA Innovations Against Poverty⁵⁰ are programs designed to counter the Pioneer Gap, although medical devices often not make it to the next rounds after the design phase.
- Some funds focus on specific medical challenges, such as Saving Lives at Birth⁵¹, which provides seed capital and funding for a scaling-up phase of medical innovations.

4.2. Political and institutional support

- **The global health community is slowly shifting focus from communicable diseases to chronic diseases and multi-vector diseases.**
 - **Many countries who are pushing for universal healthcare coverage is limiting the role of foreign NGO’s in local healthcare systems.**
- Health issues are high on the global development agenda.
 - 3 Millennium Development Goals focus directly on health topics:
 - MDG 4: reduce child mortality
 - MDG 5: improve maternal health
 - MDG 6: combat HIV/AIDS, malaria and other diseases
 - The global health community was mainly focused towards treating communicable diseases, and is now shifting to the prevention of chronic health issues which are emerging in developing countries, and more complex multi-vector diseases, such as diarrhea and respiratory tract infections.
 - In 2012 the UN passed a resolution encouraging all countries to implement universal healthcare coverage⁵². Governments are increasingly accommodation universal healthcare coverage, often pushing out NGO’s who traditionally occupied specific parts of the healthcare system.
 - Organisations such as PATH (Program for Appropriate Technology in Health) aim to link all relevant stakeholders in health innovation adoption, including governments, regulators, NGO’s and the private sector.
 - Regulatory harmonization is recognized as a key factor in speeding up access to market of innovative medical devices. However, many governments that have drafted regulations

⁴⁸ <http://www.globalpartnerships.org/impact-areas/health-services/>

⁴⁹ <http://www.usaid.gov/div>

⁵⁰ <http://www.sida.se/English/Partners/Private-sector/Collaboration-opportunities/Challenge-Funds/Innovations-against-poverty/>

⁵¹ <http://www.savinglivesatbirth.net/apply>

⁵² http://www.un.org/ga/search/view_doc.asp?symbol=A/67/L.36

make little progress in implementing or enforcing them, often due to overall institutional weakness.

4.3. Awards and recognition

Apart from criteria such as the actual achieved impact, or scientific recognition via publications, awards and recognition come in many forms.

- Fellowships such as Ashoka: Innovators for the Public⁵³
- Awards such as the Siemens Stiftung Empowering People Award⁵⁴, where in 2013 medical devices were the top-scoring category (glasses, sanitary pads, sleeping bag incubator, prosthetic knee, wheelchair for rough terrain)
- Research grants such as the Gates Foundation Grand Challenges Exploration Grant⁵⁵.
- Working with the right partners: A certain status within the industry can be derived from working with top funders such as the Bill&Melinda Gates Foundation, renowned bio-engineering or medical universities or large NGO's.

⁵³ https://www.ashoka.org/fellows?country=All&keys=&tid=All&tid_1=67&tid_2=All

⁵⁴ <http://www.empowering-people-award.siemens-stiftung.org/en/winners/>

⁵⁵ <https://me-web2.engin.umich.edu/pub/news/newsitem?newsItemId=454>

5. Poverty definition

Poverty can be defined economically as those living below a certain income threshold, typically less than 1.25 or 2 USD a day (at 2005 Purchasing Price Parity)⁵⁶. Such quantitative definitions are often criticized for not taking into account price differences between regions, excluding non-monetary income (e.g. produce from subsistence farming), or ignoring that poverty is a continuum with different levels of hardship. We follow the qualitative definition of the UN, which describes poverty in broader terms as a “lack of income and productive resources to ensure sustainable livelihoods; hunger and malnutrition; ill health; limited or lack of access to education and other basic services; increased morbidity and mortality from illness, homelessness and inadequate housing; unsafe environments and social discrimination and exclusion⁵⁷”

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7. Background on R&D state search methodology

7.1. Search Database

The database used for these analytics is Scopus, the world’s largest online database of peer-reviewed articles and abstracts, by Elsevier. Scopus covers over 50 million records from 21,000 journal titles by 5,000 publishers.

Scopus also offers advanced online search tools, covering ‘popular scientific’ publications outside of the Scopus database. Those publications include scientists’ homepages, courseware, patents, institutional repositories as well as selected web content such as reports from World Bank, OECD etc.

7.2. Search Queries

The search queries that have been used to yield the data on which this analysis is built consists of combinations of 3 search terms:

1. A search term describing the field of ‘Healthcare’
2. A search term describing specific technologies or phrases for Medical Devices.
3. A search term describing ‘Developing Countries’

⁵⁶ <http://go.worldbank.org/77LE4ON4V0>

⁵⁷ http://www.un.org/esa/socdev/unyin/documents/ydiDavidGordon_poverty.pdf